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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/695,067	10/28/2003	J. Stewart Young	MSDI-1002/PC0000767.00	5993
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Attn: Noreen Jo	ohnson - IP Legal Dep	COTRONEO, STEVEN J		
2600 Sofamor Danek Drive MEMPHIS, TN 38132			ART UNIT	PAPER NUMBER
			3733	
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			09/27/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

	Application No.	Applicant(s)		
Office Action Comments	10/695,067	YOUNG ET AL.		
Office Action Summary	Examiner	Art Unit		
	STEVEN J. COTRONEO	3733		
The MAILING DATE of this communication appeariod for Reply	pears on the cover sheet with the c	orrespondence address		
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING D - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b).	NATE OF THIS COMMUNICATION 136(a). In no event, however, may a reply be tin will apply and will expire SIX (6) MONTHS from e, cause the application to become ABANDONE	N. nely filed the mailing date of this communication. D (35 U.S.C. § 133).		
Status				
1) ■ Responsive to communication(s) filed on 10 A 2a) ■ This action is FINAL . 2b) ■ This 3) ■ Since this application is in condition for alloware closed in accordance with the practice under A	s action is non-final. ince except for formal matters, pro			
Disposition of Claims				
4) Claim(s) <u>1-21,34-46,49,51-55 and 57-65</u> is/are 4a) Of the above claim(s) is/are withdra 5) Claim(s) is/are allowed. 6) Claim(s) <u>1-21,34-46,49,51-55,57-61 and 63-6</u> 7) Claim(s) <u>62</u> is/are objected to. 8) Claim(s) are subject to restriction and/o	wn from consideration. <u>5</u> is/are rejected.			
Application Papers				
9) The specification is objected to by the Examine 10) The drawing(s) filed on is/are: a) acc Applicant may not request that any objection to the Replacement drawing sheet(s) including the correct 11) The oath or declaration is objected to by the E.	cepted or b) objected to by the I drawing(s) be held in abeyance. See tion is required if the drawing(s) is objected.	e 37 CFR 1.85(a). jected to. See 37 CFR 1.121(d).		
Priority under 35 U.S.C. § 119				
 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. 				
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal F 6) Other:	ate		

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 8/10/2010 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-7, 10-11, 16-23, 29-31, 33, 34, 43, 53, 58-61 and 63-64 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) and in view of David et al. (US 6,267,543).

Crozet et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 3), said assembly comprising an interconnection element (Fig. 3) including a first body (Fig. 3, ref. 46) and a stud (Fig. 3, ref. 50), said first body having a first aperture (Fig. 3, near aperture through which ref. 62 extends) formed therein (Fig. 3) and said stud extending from the body (Fig. 3), said first aperture including an upper portion formed having a lobed shape (Fig. 3); a first rod connector (Fig. 3, ref. 30)

including a first shaft (Fig. 3) terminating in a first rod engaging portion (Fig. 3, near ref. 18) and a lobe (Fig. 3, near ref. 62) extending laterally from an end of said first shaft (Fig. 3) and displaced axially along said first shaft from the spinal first rod engaging portion (Fig. 3); a second rod connector (Fig. 3, ref. 20) including a second shaft having a second body (Fig. 3, ref. 34) carried thereon, said second body having a second aperture formed therein (Fig. 3, ref. 40), said second aperture having the stud received therein (Fig. 3)(Fig. 2); and a fastener configured to engage with the stud (Fig. 3, ref. 56). The first aperture defines a first axis (Fig. 3) extending through the first body (Fig. 3) and the stud is positioned to lie substantially orthogonal to the axis (Fig. 3). The first shaft exhibits a substantially round cross-sectional profile (Fig. 3, near ref. 28). The first rod engaging portion comprises a curved member (Fig. 3, near ref. 18) configured to at least partially encircle a spinal rod (Fig. 3). The first rod engaging portion comprises a threaded aperture (Fig. 2, ref. 24) extending into the curved member (Fig. 2). The first shaft is substantially straight (Fig. 3). The second shaft is curved (as it has various curves, Fig. 3). The first shaft is slidably received within the first aperture to allow the first rod engaging portion to be spaced from the second rod engaging portion at varying distances (Fig. 3). The second shaft is rotatable about an axis defined by the stud to vary an angle defined by the first shaft and the second shaft (Fig. 3) The first shaft and the second shaft are curved (Fig. 3, as they have various curves, Fig. 3). The second aperture of the second shaft is configured to allow the second shaft to pivot along the axis defined by the stud (Fig. 3). The first rod connector is rotatable about an axis defined by the first shaft (Fig. 3). The second body on the second shaft includes a lower

surface, wherein engagement of the fastener to the stud urges the lower surface to contact the first shaft and clamp the first shaft in a first orientation relative to the second shaft (Fig. 4B). The first rod connector is rotatable about an axis defined by the first shaft (Fig. 3). The first rod connector is rotatable about an axis defined by the stud (Fig. 3). The second rod connector is rotatable about an axis defined by the stud (Fig. 3). The first shaft of the first rod connector and the second shaft of the second rod connector are curved (Fig. 3, as they have various curves). The assembly comprises a first spinal rod secured to the first rod engaging portion (Fig. 3, ref. 12) and a second spinal rod secured to the second rod engaging portion (Fig. 3, ref. 14), wherein the first spinal rod is positioned to lie non-parallel to the second spinal rod (Fig. 3). Engagement of the fastener to the stud secures the second rod connector in a selected orientation (Fig. 3). The first spinal rod defines a first plane and the second spinal rod is positioned to lie in a plane different from the first plane (Fig. 3). The first rod engaging portion comprises a hook (Fig. 3, near ref. 18) sized to at least partially encircle a spinal rod, said hook extending laterally from the first shaft in a first direction (Fig. 3) and wherein said lobe extends laterally from the first shaft along said first direction (Fig. 3). The assembly has a smooth exterior surface (Fig. 3). The first and second shafts are configured to nest with each other (Fig. 2). The stud is monolithic with said body (Fig. 3). The stud has a longitudinal axis, and said first shaft has a longitudinal axis, and said stud longitudinal axis is oblique to said first shaft longitudinal axis (Fig. 3). The first shaft and said second shaft are capable of pivoting with respect to each other between a first position in which said first shaft and said second shaft are substantially parallel, and a second position in

which said first shaft and said second shaft define an interior angle between them that is less than 180 degrees (Fig. 2)(Fig. 3). The second aperture has a central axis (Fig. 3), and said second rod connector has a channel for accommodating a spinal rod (Fig. 3, near ref. 20), said channel having a longitudinal axis (Fig. 3), and said central axis and said longitudinal axis are perpendicular to each other (Fig. 3).

A method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 1 (Fig. 1).

Crozet et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 3), said assembly comprising: a first rod connector (Fig. 3, ref. 18) including a first shaft terminating in a first body (Fig. 3, near ref. 18) having a channel therethrough (Fig. 3, channel which ref. 12 rests in); a second rod connector (Fig. 3, ref. 20) including a second shaft (Fig. 3) defining a longitudinal axis (Fig. 3) and terminating on a first end with a rod engaging portion (Fig. 3, near ref. 20) and on an opposite second end with a second body (Fig. 3, near ref. 36), said second body having a first aperture therein (Fig. 3, ref. 40) defining a first central axis (Fig. 3), said first end of said second rod connector also including a second aperture (Fig. 2, ref. 26) therein defining a second central axis (Fig. 3) positioned to lie at an angle to the first central axis (Fig. 3); an interconnection element (Fig. 3, ref. 44) having a third body (Fig. 3, ref. 46) that includes a third aperture (Fig. 3, aperture through which ref. 62 extends) therein for receiving a portion of said first shaft (Fig. 3) and a stud (Fig. 3. ref. 50) protruding upwardly from said third body (Fig. 3).

A method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 44 (Fig. 3).

Crozet et al. disclose a cross connector comprising an interconnection element including a first body (Fig. 3, ref. 44) having an aperture (Fig. 3, aperture through which ref. 62 extends) formed therein and a stud (Fig. 3, ref. 50) extending from said body (Fig. 3); a first spinal rod connector (Fig. 3, near ref. 18) including a first shaft (Fig. 3) having a proximal portion received within said aperture (Fig. 3) and a distal end carrying a first spinal rod engaging portion (Fig. 3, near ref. 18) configured to at least partially encircle a spinal rod (Fig. 3), said first shaft having a projection at an end of said proximal portion (Fig. 3, near ref. 62), a second spinal rod connector (Fig. 3, near ref. 20) having a second body (Fig. 3) on a proximal end (Fig. 3), a second spinal rod engaging portion on a distal end (Fig. 3, near ref. 20) and a second shaft extending therebetween (Fig. 3), wherein said body includes a second aperture (Fig. 3, ref. 40) having the stud received therein (Fig. 3)(Fig. 2); and a single fastener (Fig. 3, ref. 56) to secure the first and second spinal rod connectors to each other at a user defined orientation relative to each other (Fig. 2)(Fig. 3).

A method of treating a spinal defect, said method comprising: securing a first spinal rod and a second spinal rod each to two or more vertebrae; and interconnecting the first spinal rod to the second spinal rod using the assembly of claim 53 (Fig. 3).

Regarding claims 1 and 53, Crozet et al. disclose the claimed invention except for the first shaft and said lobe slideably received within the first aperture such that said

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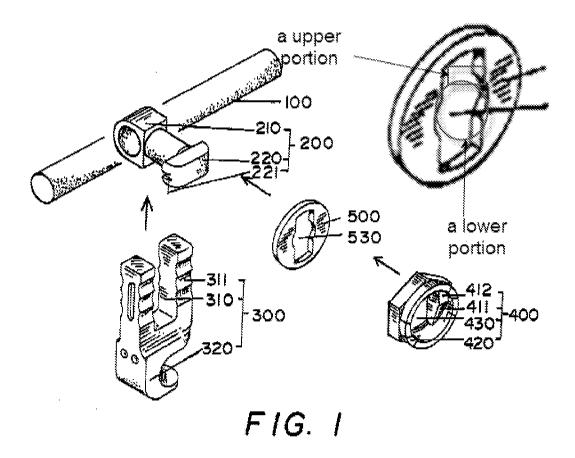
lobe passes through said first aperture and upon rotation of said first rod connector said lobe prevents said first rod connector from being removed from said first aperture; the first aperture is non-circular; rotation of the first rod connector induces the lobe to contact said first body and inhibit removal of the first shaft from the first aperture; the projection being able to move through said aperture when said shaft is in a first orientation with respect to said aperture, and being unable to move through said aperture when said shaft is in a second orientation with respect to said aperture different from said first orientation. Crozet et al. do, however, disclose a fastening mechanism comprising lobe on the end of the first shaft in order to prevent the shaft from being removed from the first aperture (Fig. 3, ref. 62)(column 5, lines 55-65).

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Lin discloses a fastening mechanism that comprises a lobed portion (Fig. 3, ref. 220) on a shaft portion (Fig. 3) and a non-circular aperture (Fig. 3 e.g. ref. 630, 730, 530, 430), the lobed portion passing through the aperture and, upon rotation, preventing the shaft from being removed from the aperture (column 3, lines 52-67). A lower portion is circular and an upper portion is non-circular.

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It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the fastening mechanism of Crozet et al. with a fastening mechanism as taught by Lin in order to achieve the predictable result of inserting the shaft and preventing a shaft from being removed from an aperture. Crozet and Lin both teach locking mechanisms and substituting one mechanism for a second would be obvious to one of ordinary skill in the art.

The projection or lobe extends from the end towards the proximal section (the lobe of Crozet and Lin is located on the end of the shaft).

Crozet in view of Lin discloses the claimed invention with the lobe or projection being able to pass through the aperture in two orientations. Crozet in view of Lin does not disclose the lobe having only one orientation to pass through the aperture.

David et al. discloses a key lock mechanism that can have two orientation (fig 1) that the lobes can pass through an aperture or can have only one orientation that allows for the lobe to pass through the aperture (fig 4). The aperture is the second configuration has a semi-circular lower portion and a non circular upper portion (fig 6).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the double lobe design (two orientations) of Crozet et al. in view of Lin with single lobe design (one orientation) as taught by David et al. in order to achieve the predictable result of allow the lobe to pass through the aperture.

Claims 8, 9, 12 and 60are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) and in view of David et al. (US 6,267,543) in view of Burgess et al. (US Pub. 2003/0114853 A1).

Crozet et al. in view of Lin and in view of David et al. disclose the claimed invention except for the first shaft being curved so as to be non-linear. Crozet et al. in view of Lin and in view of David et al. do, however, disclose the shafts extend between

and connect the rod engaging portions of the device to one another (Crozet et al., Fig. 3), which in turn connects the spinal rods to one another (Crozet et al., Fig. 3).

Burgess et al. disclose a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 6) that comprises shafts that are curved (Fig. 6, refs. 84 and 82). The shafts are used to extend between and connect rod engaging portions of the device to one another (e.g. Fig. 1), which in turn connects spinal rods to one another (e.g. Fig. 1)(Fig. 6).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have substituted the shafts of Crozet et al. in view of Lin in view of David et al. with curved shafts as taught by Burgess et al. in order to achieve the predictable result of extending between and connecting rod engaging portions of the device to one another, which in turn connects spinal rods to one another.

Having a curved rod would make a portion of the shaft to be at an oblique angle with the stud in the fixed position.

Claims 13-15, 24-28, 37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) and in view of David et al. (US 6,267,543) in view of Sherman et al. (US Pat. 5,976,135).

Crozet et al. in view of Lin in view of David et al. disclose the claimed invention except for a washer carried by the stud and positioned between the stud and the second aperture of the second rod connecting member.

Sherman et al. disclose a lateral connector assembly comprising a washer (Fig.

7, ref. 55) and the washer having splines (Fig. 7, ref. 60) and recesses (Fig. 6, ref. 58) and the second spinal rod connector having a lower surface (Fig. 11, ref. 72), which has a second set of splines (Fig. 11, ref. 82) which can matingly engage the splines of the washer, which allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19). The washer is made from a deformable material, since any material will deform when pressure is applied to it. The washer is capable of deforming when the fastener engages the stud. Engagement of the fastener can frictionally engage the washer to the first shaft of the first rod connector. The washer is capable of being carried by the stud and positioned between the stud and the second aperture of the second rod connecting member. This set-up enables the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have modified the cross-connector assembly of Crozet et al. in view of Lin in view of David et al. with a washer and the washer having splines and the second spinal rod connector with a lower surface, which has a second set of splines of Sherman et al., in order to allow the lateral connector to assume variable angular positions with respect to the washer (column 7, lines 1-19).

Claims 35, 36, 54, 55 and 57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) and in view of David et al. (US 6,267,543) in view of Shluzas (US Pat. 6,554,832 B2).

Crozet et al. in view of Lin in view of David et al. disclose the claimed invention except for the assembly comprises an insert configured to at least partially encircle said first shaft, said insert disposed within said first aperture. The insert in combination with the first aperture define a ball and socket joint. An insert disposed within the second aperture, said insert configured to at least partially encircle said stud. The insert in combination with the second aperture define a ball and socket joint. The insert is substantially spherical. The insert is substantially cylindrical.

Shluzas discloses a cross-connector assembly for interconnecting a pair of orthopedic rods (Fig. 2) that comprises an insert (Fig. 2, ref. 52) configured to at least partially encircle a shaft (Fig. 2, ref. 42) of a rod connecting member (Fig. 2) extending through a first aperture (Fig. 2, ref. 40) and positioned in a second body (Fig. 2, ref. 30) and in communication with a second aperture (Fig. 2, aperture through which ref. 58 is placed). The insert creates a ball and socket type-joint (Fig. 2)(Fig. 4)(column 2, lines 33-34), which allows for pivotal movement of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and further allows one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding allows for greater adjustability and individualization of the device.

It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the device of Crozet in view of Lin and in view of David with an insert as taught by Shluzas, in order to create a ball and socket type-joint (Fig. 2)(Fig. 4)(column 2, lines 33-34), which would allow for pivotal movement

of the rod connecting members relative to each other (Fig. 4) (column 2, lines 33-34) (column 2, lines 36-39) (column 2, lines 49-54) and would further allow one rod connector to be slidable relative to the other rod connector (column 2, lines 39-44). This pivoting and sliding would allow for greater adjustability and individualization of the device.

Claims 39-42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Lin (US Pat. 5,545,167) and in view of David et al. (US 6,267,543) in view of Schlapfer et al. (US 5,501,684).

Crozet et al. in view of Lin in view of David et al. discloses the claimed invention except for an insert disposed in the second aperture that encircles the stud.

Schlapfer et al. discloses an insert (fig 1, 21) that is positioned in an aperture of a connection device and surrounds a stud (fig 1 23) to allow for adjustment in all directions (col. 2, II. 28-29). The insert creates a ball and socket with the aperture. The insert is spherical (outside surface) and cylindrical (inside surface).

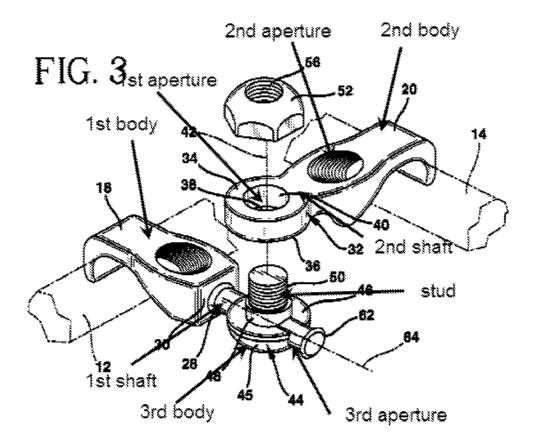
It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Crozet et al. in view of Lin in view of David et al. with an insert disposed in the second aperture that encircles the stud in view of Schlapfer et al. in order to allow for adjustment in all directions.

Claims 44-46, 49, 51 and 52 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Crozet et al. (US Pat. 6,217,578 B1) in view of Schlapfer et al. (US 5,501,684) and in view of Finn et al. (US RE39035).

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Crozet et al. discloses a cross-connector assembly (see fig 3 below) for interconnecting a pair of orthopedic rods comprises: a first rod connector (fig 3, 18) including a first shaft (fig 3, 28) terminating in a first body (fig 3, 30) having a channel therethrough; a second rod connector (fig 3, 20) including a second shaft defining a longitudinal axis and terminating on a first end with a rod engaging portion (fig 2, 22) and on an opposite second end with a second body a first aperture therein defining a first central axis (fig 3, 40). The first end of the second rod connector also has a second aperture (fig 2, 26) therein defining a second central axis positioned to lie at an angle to the first central axis. An interconnection element having a third body that includes a third aperture (fig 4, 58) therein for receiving a portion of the first shaft and a stud (fig 3, 50) protruding upwardly from the third body connects the first and second connector. A fastener (fig 3, 52) is received on the stud.



Crozet et al. discloses the claimed invention except for an insert disposed in the second aperture that encircles the stud and a fastener that extends through the first aperture and into an internal recess in the insert to fix the orientation.

Schlapfer et al. discloses an insert that is positioned in an aperture of a connection device and surrounds a stud and a fastener (fig 10, 11g) that extends through the first aperture and into an internal recess in the insert to allow for adjustment in all directions (col. 2, II. 28-29) (motion allowed until the fastener is fully clamped col. 2, II. 32-33). The insert includes a slit (fig 2, 27) extending along the vertical axis and has recesses (bottom part of fig 2, 24).

It would have been obvious at the time of the invention to one of ordinary skill in the art to modify the device of Crozet et al. with an insert disposed in the second aperture that encircles the stud in view of Schlapfer et al. in order to allow for adjustment in all directions.

Crozet in view Schlapfer et al. discloses the claimed invention except for the insert having a lower surface having a concave portion.

Finn et al. discloses an insert (fig 4, 70) having a concave lower portion to be sized and shaped to engage a shaft (col. 5, II. 26-34).

It would have been obvious at the time of the invention to modify the device of Crozet in view of Schlapfer et al. to include a concave portion on the lower portion in view of Finn et al. in order to sized and shaped to mate with the shaft. (Fig 3 above of Crozet shows the shaft of first member to extend above the top surface of the stud. A concave bottom surface of the insert would ensure a positive connection between the insert and the first member leading to a more solid construct as is the case with Finn.)

Allowable Subject Matter

Claim 62 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to STEVEN J. COTRONEO whose telephone number is (571)270-7388. The examiner can normally be reached on M-F 730-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. J. C./ Examiner, Art Unit 3733

/Eduardo C. Robert/ Supervisory Patent Examiner, Art Unit 3733